Rational Pharmaceutical Management Plus
Participation in a Rapid Assessment in Tanzania for the President's Malaria Initiative, August 8-12, 2005: Trip Report

Rima Shretta

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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Contents

Acronyms

ACT	Artemisinin based Combination Therapies
ADDO	Accredited Drug Dispensing Outlet
ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ARV	Antiretrovirals
CDC	Centers for Disease Control and Prevention
CHMT	Council Health Management Team
DHC	District Health Council
DHS	Demographic and Health Survey
DMIS	Drug Management Information System
DMO	District Medical Officer
EABL	East African Botanicals Limited
GFATM	Global Fund to Fight AIDS, Tuberculosis & Malaria
GOT	Government of Tanzania
HMIS	Health Management Information System
IEC	Information, Education and Communication
IHRDC	Ifakara Health Research and Development Centre
IMCI	Integrated Management Childhood Illness
IRS	Indoor Residual Spraying
IPT	Intermittent Preventive Treatment
IRS	Indoor Residual Spraying
JICA	Japan International Cooperating Agency
JSI	John Snow, Incorporated
ITNs	Insecticide Treated Nets
LLIN	Long Lasting Insecticidal Nets
MAC	Malaria Action Coalition
M&E	Monitoring and Evaluation
MEMS	Mission for Essential Medical Supplies
MMSS	Malaria Medicines and Supply Service
MoH	Ministry of Health
MSD	Medical Supplies Department
MSH	Management Sciences for Health
NEDLT	National Essential Drugs List of Tanzania
NTC	National Therapeutics Committee
NMCP	National Malaria Control Program
PHR Plus	Partners in Health Reform Plus
PMI	President's Malaria Initiative
PSI	Population Services International
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RPM Plus	Rational Pharmaceutical Management Plus
SEAM	Strategies to Enhance Access to Medicines

SP	Sulfadoxine-Pyrimethamine
STI	Sexually Transmitted Diseases
TANAAM	Tanzania NGO Alliance Against Malaria
TB	Tuberculosis
TFDA	Tanzania Food and Drugs Administration
TNF	Tanzania National Formulary
TNVS	Tanzania National Voucher Scheme
USAID	United States Agency for International Development
USD	United States Dollars
VAT	Value Added Tax
WHO	World Health Organization
WR	WHO Representative in Tanzania

Background

Management Sciences for Health's (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program has received funds from USAID to develop strategies to implement malaria policies and to provide technical assistance in pharmaceutical management issues for malaria. RPM Plus is a key technical partner in the USAID Malaria Action Coalition (MAC) and is providing direct technical assistance to Roll Back Malaria Secretariat.

USAID requested support from RPM Plus to provide assistance in planning for the implementation the new President's Initiative on Malaria in Africa. Announced in June 2005, this initiative seeks to "*dramatically reduce malaria as a major killer of children in sub-Saharan Africa"* by rapidly scaling up proven malaria prevention and treatment interventions, including treatment with artemisinin-based combination therapies (ACTs), intermittent preventive treatment (IPT) of pregnant women with effective antimalarials, distribution of insecticide treated nets (ITNs), and indoor residual spraying (IRS).

To lay the groundwork for the initiative in Tanzania, USAID-Tanzania and the Centers for Disease Control and Prevention (CDC), partners in the initiative, commissioned a rapid assessment report of malaria activities in the country. The resulting report will provide a basis for initial discussions within USAID-Tanzania and the CDC as well as constitute a starting point for discussions with the Government of Tanzania (GoT) and the development partners working in health.

Purpose of Trip

Rima Shretta of MSH/RPM Plus traveled to Dar es Salaam as a country rapid assessment team member along with representatives from USAID, WHO and CDC. The team was made up of Mr. Matt Lynch, of USAID/Global, Dr. Patrick Kachur from CDC, Dr. Rene Salgado a consultant hired by USAID/Tanzania, Dr. Noel Chisaka from WHO/AFRO, and Rima Shretta. Ms. Shretta led a component of the assessment that focused on the access to and availability of antimalarials, particularly ACTs. The results of this assessment will contribute to the planning for continued support for USAID/Tanzania under the new malaria initiative.

Scope of Work

As part of a larger mapping/assessment exercise, Rima Shretta assessed the current status of ACT procurement and availability in Tanzania. This included:

1. Participation in meetings
2. Provision of an arrival/departure briefing to USAID/Tanzania.
3. Evaluation of the current status of ACT procurement via GFATM and other donors, including anticipated quantities and timelines for delivery.
4. Assessment of the ACT distribution plans via the public sector.
5. Review of the status of the ACT distribution by the private sector, in terms of drug registration and government policy.

6. Estimation of ACT quantities that may be procured by the US Government within the next six months.
7. Provision of recommendations for an appropriate policy environment that will allow effective ACT distribution by the private sector.

Activities

1. Participation in Meetings

World Vision

Mr. Joseph Mashafi
A meeting was held with World Vision to discuss their role in the Tanzania National Voucher Scheme (TNVS) which included discussion on their support to the NMCP for training in ITNs and IPT. The details of the discussion at this meeting are included in Annex 2.

As part of the TNVS to provide subsidized ITNs to pregnant women via Antenatal Care (ANC), World Vision (WV) and CARE began providing training to ANC staff in voucher use and IPT at the sub-district level in September 2004.

Gaps in this program identified by partners included supply irregularity of SP for IPT due to poor drug management practices in some districts and facilities, a lack of a strong and coherent communications strategy to and inadequate supervision at the district level for both IPT and ITNs. In addition, the program does not cover the rest of the under five population. Another major gap identified in the program was the training of retailers in re-treatment.

WHO

Dr. Ritha Njau (WHO NPO for Malaria)
Dr. Njau informed us that her unit was working closely with NMCP on the implementation of ACTs and that there were plans for a nationwide implementation in Tanzania. The Italian Corporation has a full-time technical person seconded to NMCP for assistance with activities related to ACT implementation. One of the organizational problems was that the NMCP was not placed very highly in the MoH hierarchy and this had a consequence on programmatic success. There was some discussion on the private sector and, while the NMCP and partners acknowledged that methods for making ACTs available in the private sector must be sought, detailed discussions on potential strategies had not begun.

NMCP

Dr. Alex Muita (Program Manager)
Dr. Renata Mandike (Deputy Program Manager)

Drs. Muita and Madike gave an overview of plans for ACT implementation and the current status of diagnostic capability in the country. Detailed discussions are presented in annex 2.

The NMCP is spearheading the overall malaria laboratory capacity strengthening. As ACTs are 10-20 times more expensive than SP the MoH is considering ways to improve diagnostic accuracy of malaria. The NMCP is seeking to implement RDTs initially on a limited basis and later expand it to other lower level health facilities.

In August of 2004 the Task Force on Malaria Treatment Policy recommended that Tanzania move away from SP and adopt Artemether-Lumefantine (Coartem®). Currently Tanzania has funds from Round 4 of the GFATM for procurement of Coartem. They have ordered 8.7 million courses of treatment of Coartem from Novartis through WHO (MMSS) for the first 6 months of implementation. Communication and mass campaigns for the change to ACTs at national and community levels will be done by PSI and Tanaam.

The first draft of the new treatment guidelines which include ACTs has been completed. A revision of the new Tanzania National Formulary[1] is currently at the printing level. The National Essential Drugs List of Tanzania (NEDLT) is also currently being revised and will need to incorporate the new treatment.

The change to ACT will require re-training. The NMCP will use a cascade training scheme beginning with national trainers in August 2005 through to the peripheral levels. It is expected that this will be completed in November 2005.

MSD

Mr. Missanga Muja (Procurement Manager and Acting Procurement Director)
Mr. Dickson Mwamwembe (Director of Logistics)

Details of the discussions of this meeting are given in annex 2.

The Medical Stores Department (MSD) is responsible for procurement, storage and distribution of medicines to all public sector facilities. Some Mission facilities also get their medicinal supplies from MSD. For this service, MSD charges the MoH 15% of the shipment costs. Only drugs that are under the National Essential Drugs List of Tanzania (NEDLT) are supplied.

The procurement of Coartem as described above will be done under WHO-agreed procurement mechanisms with Novartis. MSD will thus carry out customs clearance, storage and distribution.

TFDA

Mr. R.L. Mhangwa; Director of Product Registration
Mr. Henry Irunde; Pharmacovigilance
Mr. Chukilizo; Head of Drug Registration

Details of the discussions of this meeting are given in annex 2.

TFDA authorizes import of all products which are also inspected for quality at the entry point. The registration procedure also requires product quality testing and GMP inspection.

[1] Last revised in 1998

Currently all medicinal products for consumption in Tanzania must be registered by the TFDA. Products are registered for five years after which the registration must be renewed. Coartem (artemether/lumefantrine, 20/120) was registered by TFDA in June 2000. The product registration was due for renewal in June 2005. At the time of conducting the interview with the head of registration at TFDA, no renewal for Coartem had been received.

In addition to its functions as a regulatory body and product quality assurance, the TFDA also is responsible for monitoring of adverse drug reactions (ADRs).

IMCI

102 districts in Tanzania are implementing IMCI. The IMCI course is being modified to include ACT treatment focusing on children under five years or age. Algorithms and charts will be modifies as soon as the official announcement by the MoH of the change is made. For the IMCI course, which is 11 days long, the estimated cost is USD $6.5 million. An abridged version of the course has been developed and tested with senior managers. Currently the IMCI course is run separately from the NMCP course. There are discussions underway to add the adult component to the IMCI course to establish a link. There are IMCI/Malaria focal persons in each district.

MSH

Dr. Romauld Mbwasi

Details of the discussions of this meeting are given in annex 2.

Discussions were held with Dr. Mbwasi of MSH who is implementing the MSH/MoH Accredited Drug Dispensing Outlet (ADDO) pilot strategy. The ADDOs are privately operated outlets authorized to sell a range of essential drugs classified as prescription-only with training and supervision from national and local drugs regulatory authorities. ADDOs will eventually replace Part II drug stores. Currently only about 100 ADDOs exist in the Ruvuma Region where the concept was pilot-tested by TFDA and MSH's Strategies to Enhance Access to Medicines project (SEAM).

WR debriefing

A debriefing of the President's Malaria Initiative was made to the WHO Representative in Tanzania on Friday 12th August. A presentation of the key findings and recommendations were made. The WR was in agreement with the recommendations.

Participation at Ifakara Meeting

The team participated in the CDC/IHRDC meeting on Thursday 11th August during which presentations were made by the NMCP, CDC/IMPACT, IHRDC and MSH.

Chief Pharmacist's Office

The Chief Pharmacist was not available for a meeting however, discussion with staff at his office determined that there were no import taxes or VAT on pharmaceuticals. However, all imported products incur a charge of 2.5% payable to the pharmacy board (importation fee).

2. Provision of an arrival/departure briefing to USAID/Tanzania

A debriefing was held with Dr. Pamela White at USAID to discuss the findings of the assessment and the preliminary recommendations for achieving short term "quick wins" for the President's Malaria Initiative. A presentation was made by Dr. Rene Sagaldo with input from the rest of the team.

3. Evaluate the current status of ACT procurement via GFATM and other donors, including anticipated quantities and timelines for delivery.

The funds available from Round 4 of the GFATM is USD $54,201,787, 85 percent of which will be used for procuring ACT (Coartem). The end date for this grant is May 31, 2007, after which other sources for procuring ACTs will need to be identified.

The NMCP used SP estimates at sentinel sites to give information on the number of malaria cases every month. These estimates were used to calculate the quantities of ACTs needed in Tanzania. They have ordered 8.7 million courses of treatment of Coartem from Novartis through WHO (MMSS) for the first 6 months of implementation. These will be delivered in two shipments in January and March 2006 respectively. A second order will be placed of the same quantity for the following six months. The NMCP plans to begin ACT implementation in April 2006 after receiving the first two shipments of Coartem.

According to the MoH the agreement with GFATM, Coartem® will be purchased through WHO. However, WHO charges a 3 percent overhead cost. The NMCP believes that purchasing directly from Novartis will produce savings. It is unclear whether Novartis would be willing to sell directly to national programs at the WHO rate outside the WHO mechanism.

A recent observation in the CDC IMPACT trial found that the availability of ACTs in Rufiji district increased public sector utilization by 20%. However, the long-term impact of this is unclear and provisions for the potential increased utilization of the public facilities have not been taken into consideration when estimating quantities of ACTs needed.

4. Assessment of the ACT distribution plans via the public sector

The timeline for implementation of ACTs presented in Annex 1.

The country hopes to use the experience from the SP change to implement a country wide implementation using staggered deliveries of the treatments to the health facilities.

The Medical Stores Department (MSD) is responsible for procurement, storage and distribution of medicines to all public sector facilities. The procurement of Coartem as will be done under WHO-agreed procurement mechanisms with Novartis. Unless the government is able to negotiate direct

procurement from Novartis, the Medical Stores Department's (MSD) responsibility will begin when the product lands in Tanzania. MSD will be responsible for clearance, storage and distribution (and re-packaging, if needed) of all health products for the MoH. Usually it takes 14-21 days for goods from arrival at the port to storage at MSD.

While MSD has a system of open competitive tendering for all government procurements, the government policy allows for single or limited source products (as in the case of ACTs) to be procured without open tenders.

The MSD has national and zonal warehouses and while currently, there is little storage capacity to accommodate large numbers of stocks, they have recently acquired an additional warehouse that will be used for malaria and other selected drug products.

Two systems of distribution exist currently in Tanzania; the "push" system which uses Essential Drug kits and the "pull" or indent system. In the former, each level of health facility receives a pre-determined quantity of kits of standard content while in the latter facilities decide on the quantity of products that are required and order these from MSD accordingly. Tanzania is in the process of converting the entire country to a pull system. So far, 47 districts out of a total of 120 are implementing a pull system while the rest still receive kits. It is expected that all the districts will convert to the indent system by 2007.

MSD distributes health commodities to all the MSD zonal stores which supply the districts. The responsibility of MSD ends at district level. The District Medical Officer's (DMO) office supplies health facilities within the district.

Although orders are placed by MSD annually (following the annual tender), kits are delivered every two months. In addition, MSD keeps 2 months of buffer stock. Under the indent system, deliveries are done every 3 months and three months of buffer stock is kept at MSD. Anything with an expiry date of less than 3 months is not issued.

Health facilities send orders directly to MSD, but the DMO distributes them from the district level downwards. The health facilities are theoretically supposed to send copies of the orders to the DMO, but in practice they do not. The district has its own funds for purchase of the drugs. However, the bottom line is fixed according to the kit budget.

The contents of the kits are determined by the Drugs and Therapeutics committee. Under the push system, the NMCP instructs the MSD what quantities of antimalarials to include in the kits. Currently, the kits contain SP, amodiaquine and quinine. The SP for malaria treatment will be replaced with Coartem. However, consumption data for SP for IPT only is not available and the quantity of SP to replace has not been determined yet. Kit items have not been revised yet. SP quantities have already been reduced partly because excess quantities had previously been supplied due to errors in calculating need[2]. Amodiaquine has not started to be phased out yet but it is expected that quantities will start to be reduced.

[2] When Tanzania changed from chloroquine to SP, the quantity of SP to be ordered was substituted tablet for tablet for SP resulting in excess SP stock (chloroquine tablets are taken every 6 hours over the course of four days while SP tablets are taken as a single dose).

A new tender for kits is being prepared for October 2005. It is expected that these new kits will contain the revised list of antimalarials. Expected delivery is April/May 2006 (6 months after tender). This coincides with the expected date of implementation of the new ACTs. It will be crucial for MSD and the NMCP to liaise and plan closely so that the facilities have the new first line drug at the same time the IEC messages are transmitted.

Meetings between the MSD and the NMCP were conducted two weeks before this rapid assessment to discuss the logistics of supplying the new ACTs. As Coartem procurement is carried out under a different system from the other drugs in the kits and the kits already arrive packed at MSD, there are two options; the kits will either have to be repacked by MSD so that the Coartem can be placed in the kits or, there will need to be an additional kit for the Coartem. There have been discussions that suggest that the latter option may be more feasible due to the bulky nature of the prepackaged Coartem.

There is a repackaging facility at MSD. The cost for re-packaging (for items under the indent system) is Tsh 20,000 (approx. USD 20) per facility. It has not been determined what the charge would be if the new kits will have to be re-packaged. MSD has requested NMCP to provide a sample in order to determine costs.

There are no plans for additional security for ACTs. ARVs and narcotics are kept in locked cages within the warehouses and trucks are always locked during the dispatch process.

Currently, when MSD receives products the batch numbers and expiry dates are recorded and there is a system for issuing products that have shorter expiry dates first. There are no systems for product exchange among the districts. However, near-expiry products in a facility may be given to another facility within the same district that is likely to consume it before it expires. However, this will depend on the initiative of the district pharmacist and there are no set procedures to ensure that this occurs. There are no systems to return near expired products to the MSD. Expired products are destroyed at the district level.

MSD also does random sampling and takes the samples to the Tanzania Food and Drugs Authority (TFDA) or the government laboratory for testing. In addition some samples are taken at random and subjected to testing using a minilab at MSD itself. TFDA also randomly collects samples from MSD for testing (particularly antimalarials, TB medicines, antiretrovirals and some antibiotics).

There is a gap in information exchange from the MSD level to the peripheral levels mainly due to the decentralized system. Currently with the indent system, there are delays with facilities bringing orders due to a lack of experience with forecasting needs. Furthermore, Drug Management Information Systems (DMIS) are poor and there is a lack of consolidated data at the various levels on utilization or consumption.

Communication and mass campaigns for the change to ACTs at national and community levels will be done by PSI and Tanaam, however detailed plans have not been done.

The first draft of the new treatment guidelines which include ACTs has been completed and it is currently being circulated for comments. The draft will be used as an orientation guide during the first training of trainers in mid-August 2005 after which they will be finalized.

A revision of the new Tanzania National Formulary[3] is currently at the printing level. Therefore, an addendum incorporating the new recommendations will be made. The National Essential Drugs List of Tanzania (NEDLT) is also currently being revised and will need to incorporate the new treatment however these processes will only begin when an official announcement of the new policy is made.

The change to ACT will require the re-training of approximately 9,200 health workers by the NMCP and IMCI. NMCP will use a cascade training scheme beginning with national trainers in August 2005 through to the peripheral levels. It is expected that this will be complete in November 2005. Upon finalization of the new guidelines the IMCI training manuals, charts and algorithms, the reproductive health guidelines and any other guidelines with a malaria component will then be revised to include the new ACT as well as issues of laboratory diagnosis.

There is little provision in the entire scheme for follow up and supervision after initial training has been done.

NMCP partners for ACT policy implementation include:

- IHDRC (Pharmacovigilance and to measure the effect of policy implementation)
- NIMR
- TFDA (regulatory, QC, Pharmacovigilance)
- PSI (Mass media)
- TaNaam (Communication in communities)
- CHMT (Implementation)
- Communities (Implementation)

Other challenges identified by the NMCP that are still under discussion are compliance and ensuring rational drug use, the treatment of choice in pregnant women and children < 5kg. Drug management is also a challenge as currently two systems of distribution are operating in the country; the push and pull system. Discussions are underway with MSD to determine incorporating ACTs within existing distribution systems. The NMCP recognizes a need to strengthen inventory management and drug management at the district pharmacy and health facility levels.

Currently all medicinal products for consumption in Tanzania must be registered by the TFDA. Products are registered for five years after which the registration must be renewed.

Coartem (artemether/lumefantrine, 20/120) was registered by TFDA in June 2000. The product registration was due for renewal in June 2005. At the time of conducting the interview with the head of registration at TFDA, no renewal for Coartem had been received. Although the registration for Coartem has expired, the TFDA will honor their registration provided the manufacturer submits the renewal soon.

[3] Last revised in 1998

WHO now recommends that Coartem be used for three days (6-doses) in high transmission areas such as Tanzania instead of the original recommended duration of two days (4 doses). For the purposes of registration, the increased duration of treatment requires a notification by the manufacturer to TFDA by way of a letter. No new registration for the change in duration of treatment is requires and no new dossiers need to be submitted.

To ensure availability of the new products at the lowest levels of care, the ACTs regulatory status will have to be changed from a "prescription-only status" to an "over-the-counter" or "general sales list status". This requires a recommendation by the National Drugs and Therapeutic committee to the TFDA. The legal department within the TFDA reviews the implication of this change and authorizes the change in regulatory status. This process has not yet begun.

5. Review the status of the ACT distribution by the private sector, in terms of drug registration and government policy.

Coartem is currently available in the private sector for USD $8-$9. This price is out of reach by the majority of the populations at risk of malaria. While the NMCP recognizes that this fact must be dealt with in the near future, discussions on private sector delivery have not proceeded beyond this recognition. Ways to deliver sustainable subsidies using public/private partnerships will be necessary to reach the populations that do not seek treatment in the public sector.

There are plans to roll out the ADDOs to 2 additional regions in 2005-6: Morogoro, with support from USAID, and Rukwa, with direct support from the Government of Tanzania. No resources are as yet available for providing a subsidized ACT through these shops. However, the ADDOs may be a potential opportunity for a public/ private sector initiative.

Rapid Survey of drug shops (Duka La Dawa Baridi) and Pharmacies

A mini sample survey of some private pharmacies carried out in Dar es Salaam town during the course of this rapid assessment on the type of antimalarials available and their prices is shown below. The cost of these medicines in the private sector ranged from $5.0 for mono therapy to at least $9.0 for combined therapy.

Table 1. Antimalarial drugs found in the private sector pharmacies and costs

Drug	Cost (TSh)
Fansidar (sulfadoxine-pyrimethamine)	300-350
Artesunate (local)	1500-2000
Coartem (artemether-lumefantrine)	8000 - 9000
Chloroquine	Not stocked
Halfan (halofantrine)	12,000-13000
Arinate (Artesunate-Dafra)	5500-6000
Artemether	3500 -6000

SP(Roche)	1200-1300
SP Other	275-325
Metakelfin (sulfamethoxazole-pyrimethamine)	300-325
Amodiaquine	300-325
Quinine	2000-2500
Artesunate (India)	2500-3000
Artekin (dihydroartemisinin-piperaquine)	4500-5000
Artesunate (Sanofi)	6000-7000

It must be noted that no antimalarials were available in the *duka la dawas* (drug shops).

6. Estimation of ACT quantities that may be procured by the US Government within the next six months.

An analysis by PHR Plus of the Financing Requirements of ACTs in Mainland Tanzania (February 2005) showed that there will be significant gaps in financing. For years 2006, 2007 and 2008, the deficit will be approximately USD $1.5, 9 and 29 million respectively. When GFATM Round 4 funds end in mid-2007, the gap in years 2009 and 2010 is approximately USD $48 – 49 million each year. These figures are for supplying public health facilities only. The deficit grows even larger if private drug sellers are considered or if utilization of the public sector increases.

A similar analysis carried out by NMCP and partners estimated the gap in funding for Coartem at 35% utilization of the public sector of USD 14 million in 2006, USD 4.8 million in 2007 and USD 9.1 million in 2008. An increase in utilization of the public sector to 50% will increase this gap to USD 27.7 million in 2006, USD 21.6 million in 2007 and USD 27.5 million in 2008. A detailed analysis will need to be carried out to triangulate these estimates.

The NMCP anticipates a shift in care sought for fever from the private to the public sector once the effectiveness of ACT is known in communities. This shift has been seen in research carried out in Tanzania and can be as high as 20 percent. When estimates for the procurement of ACT were prepared for the GFATM proposal, the shift in care seeking was not yet known. As a consequence, ACT estimates are low compared to the expected need. Given the rate of training implementation the need to supplement current requests for ACT will not be occur until late FY 2006.

Current GFATM funds for the procurement of ACT are scheduled to end mid 2007. It is expected that the NMCP will request additional funds from GFATM to continue a reliable supply of ACTs in health facilities. However, in the event that that GFATM is having difficulties in replenishing its funds there will be a shortage of funding for ACT procurement in Tanzania. The USG other donors will need to be prepared to top off government resources for procuring ACT in mid-2007 and beyond. US government funds will not be required to procure ACTs in the next 6 months unless a shortfall is experienced due to higher than expected rises in utilization.

7. **Provide recommendations for an appropriate policy environment that will allow effective ACT distribution by the private sector.**

As has been discussed earlier, up to 70 percent of cases of fever for which support is sought look for such help in the private sector. With the rolling out of ACT, which is only available at subsidized prices in the public sector, there will be a significant gap of appropriate management of fever as well as leakage from the public to the private sector. Although the private sector already is selling ACTs, they are very expensive and unreachable to all but the richest in the country. The MoH is collaboration with its partners should consider mechanisms for making ACTs available in the private sector at low cost. The mechanism for doing this would be by subsidizing the ACTs either at the source or at the delivery level. Negotiations with Novartis by officials in Zambia led to making Coartem available through selected pharmacies in a pilot project at the same subsidized price as was available for the public sector however, procurement was carried out through the public system. However, the subsidized price is no longer available for this sector and until the supply issues with Coartem are resolved, it is unlikely that this discussion will resume.

One mechanism for distribution of a subsidized commodity would be using an ADDO model.

Next Steps

Immediate Follow-up Activities

- Complete report

Recommendations

Short-term

1. Support for ACT implementation training process, especially at sub-district level

Local health councils are hard pressed to find the resources needed to pay for training and as a result often health workers do not receive training that national programs consider important. A rough estimate of the cost per health worker trained is USD $150 and up to 9,200 health workers will need to be trained in the new ACT. Although the NMCP hopes to finish the new training by 2006, it is unlikely that such goal can be achieved given the scarcity of resources and this may be potential area for PMI resources.

2. IEC/Communications assistance for ACT launch

NMCP estimates that USD $2-$3 million will be needed during the first two years of the roll out. This may be a potential area for PMI resources.

Medium Term

3. Provide technical assistance to NMCP and MSD for supply and distribution of ACTs

While the NMCP anticipates a country-wide implementation, no detailed distribution plan has been made and strategies on how to ensure an uninterrupted supply of antimalarials have not been developed. This will be essential to achieve the goals of the PMI as well as the Abuja targets.

4. Purchase ACTs to cover treatment shift to public sector after implementation

The NMCP anticipates a shift in care seeking for fever from the private to the public sector once the effectiveness of ACT is known in communities. This shift has been seen in research carried out in Tanzania and can be as high as 20 percent. When estimates for the procurement of ACT were prepared for the GFATM proposal, the shift in care seeking was not yet known. As a consequence, ACT estimates are low compared to the expected need. Given the rate of training implementation the need to supplement current requests for ACT will not be occur until late FY 2006.

5. Improved supervision and follow-up training for health workers on IPT

A critical need for the NMCP is to improve all aspects of its supervision and quality assurance. IPT in particular needs to be singled out as in dire need of supervision improvement.

6. Rapid diagnostic tests implementation in highlands

Support for this activity may include the development of training materials, including improved patient counseling.

7. Provide technical assistance for strengthening the DMIS system

A functioning DMIS system will be crucial for determining ACT consumption patterns. This will be needed to develop accurate forecasts of future need.

Long-term

8. Support ACT procurement once GFATM funds end

Current GFATM funds for the procurement of ACT are scheduled to end mid 2007. It is expected that the NMCP will request additional funds from GFATM to continue a reliable supply of ACTs in health facilities. However, it is well known that GFATM is having difficulties in replenishing its funds. This may lead to a shortage of funding for ACT procurement in Tanzania. If the NMCP is not able to meet ACT needs there can be catastrophic consequences as no viable alternative will be available. USAID, CDC and other donors need to be prepared to top off government resources for procuring ACT in mid-2007 and beyond.

9. Subsidize private sector sales of ACTs

As is reported, up to 70 percent of cases of fever for which support is sought look for such help in the private sector. With the rolling out of ACT, which is only available at subsidized prices in the public sector, there will be a significant gap of appropriate management of fever. Although the private sector already is selling ACTs, they are very expensive and unreachable to all but the richest in the country. USAID and CDC should consider mechanisms for making ACTs available in the private sector at low cost. One such mechanism can be the ADDO model.

10. Stronger links to IMCI, TFDA and MSD

Although NMCP, IMCI, TFDA and MSD meet regularly, there are still discrepancies in their approaches. For example, the NMCP and IMCI training activities do not appear to be well coordinated. One area of support may be the provision of human resource support to the IMCI program and technical assistance to make the links amongst the programs stronger and more effective.

11. Operations research

The NMCP is embarking into areas that are relatively new (e.g. roll out of ACT, introduction of LLINs, RDTs) for which not all implementation issues have been resolved. Support should be provided to the NMCP to develop and implement an operations research agenda that responds to implementation problems.

Annex 1: Timeline for Implementation

Proposed timeframe for introduction of ACT (1)

	2004		2005		2006	
	1st	2nd	1st	2nd	1st	2nd
Revision, printing and dissemination of guidelines		>>>	>>>			
Training of HW using updated training modules			>>>	>>>		
Review supply and distribution system for ACTs and diagnostics at all levels and carry out recommendations			>>>	Introduction ↓		
Procurement and storage of ACT and diagnostics for public and not-for-profit sector				>>>	>>>	>>>
Training of district pharmacist and health facilities in charges on drug and diagnostics stock management				>>>		

Proposed timeframe for introduction of ACT (2)

Introduction

	2004		2005		2006	
	1st	2nd	1st	2nd	1st	2nd
Development of a Communication strategy - IEC, BCC	>>>	>>>				
Update and agree on IEC messages on new treatment guidelines				>>>		
Sensitise public leaders and journalists about the new antimalarial drug policy				>>>	>>>	>>>
Conduct sensitization campaign using mass media and interpersonal communication channels on the new antimalarial drug policy				>>>	>>>	>>>
Develop strategies for subsidized ACT through the private sector			>>>	>>>		

Annex 2: Detailed Discussions at Meetings

World Vision

Mr. Joseph Mashafi

As part of the TNVS to provide subsidized ITNs to pregnant women via Antenatal Care (ANC), World Vision (WV) and CARE began providing training to ANC staff in voucher use and IPT (2 days) at the sub-district level in September 2004. This training program is currently about halfway through its planned course, with 3268 providers in 11 regions trained as of June 2005. The target is to train 7529 providers in 115 districts. It is expected that this will be completed in February 2006. The training material has been developed by the Reproductive and Child Health Units at the MoH. At the district level, WV and CARE work with the CHMT and DMO who identify a focal person who then acts as a co-facilitator in training at lower levels. This is usually the district malaria coordinator or the RH coordinator. Training at lower levels is coordinated by the CHMT. Some refresher training in the field occurs whenever possible. Monitoring of the training is carried out quarterly in two districts per region. The cost of the training is approximately USD 40 per person trained (excluding materials (Tsh 5000) and transport (Tsh 800)). This activity is carried out using funds from GFATM.

The vouchers for ITNs are distributed by MEDA. They also follow up and monitor their distribution. There was some leakage of vouchers in small numbers in earlier phases but this has not been seen in the current phase.

The WV/Care contract ends in 2006 however an extension of one year is being discussed during which supervision and follow up will be carried out.

Gaps in this program identified by partners included supply irregularity of SP for IPT due to poor drug management practices in some districts and facilities, a lack of a strong and coherent communications strategy to address consumer and provider concerns about SP and inadequate supervision at the district level for both IPT and ITNs. Furthermore, there are limited funds available for refresher training. Both World Vision and the JHPIEGO/ACCESS project are planning to address improved supervisory tools and training for Focused Ante-Natal Care (FANC) in the next year, in conjunction with the Reproductive and Child Health Unit at the MOH. The program does not cover the rest of the under five population and the NMCP wants to expand the voucher scheme to include other children under five. Between WV, CARE and MEDA, they have the tracking systems to be able to do this. Another major gap identified in the program was the training of retailers in re-treatment.

NMCP

Dr. Alex Muita (Program Manager)
Dr. Renata Madike (Deputy Program Manager)

Drs. Muita and Madike gave an overview of plans for ACT implementation and the current status

of diagnostic capability in the country. Detailed discussions are presented in annex 2.

The Ministry of Health policy for malaria diagnosis is dependent on the level of care. At the primary health care level (dispensaries), the principal tool for diagnosing malaria is mainly clinical utilizing the Integrated Management of Childhood Illness (IMCI) case management protocol. At health centers some microscopy exists but again diagnosis is mainly clinical. Diagnosis for severe malaria at district and zonal hospitals and other referrals hospital is parasitological via microscopy. The NMCP is spearheading the overall malaria laboratory capacity strengthening. With the advent of ACT which is 10-20 times more expensive than SP the MoH is considering ways to improve diagnostic accuracy of malaria.

The NMCP is seeking to implement RDTs initially on a limited basis in 10 of the 114 districts in the mainland with a population of 2.5 million and later expand it to other lower level health facilities. The NMCP estimates that approximately USD $ 500,000 will be needed to buy tests. Costs for training, logistics, and training materials have not been estimated and a definite plan for this has not been made. Health workers will need to be specifically trained on what to do when an RDT is negative. Suggestions have been made in Tanzania that the RDTs be reserved for use in diagnosing adult malaria cases.

In August of 2004 the Task Force on Malaria Treatment Policy met to discuss the potential of changing the treatment regimen from sulfadoxine-pyrimethamine (SP) to a more effective anti-malarial. Data from 8 sentinel sites (Kibaha, Kigoma, Dodoma, Mwanza, Masai, Kilombero, Kyela and Muheza) showed steadily increasing resistance to SP since its introduction in 2001. Clinical and parasitological treatment failure rates of 22.8% and 44.9% respectively were obtained. Resistance to amodiaquine showed 4.7 and 18.7 percent treatment parasitological failure respectively. The Task Force recommended that Tanzania move away from SP and adopt antimalarial combination therapy for malaria case management. The preferred choice for the change was a fixed-combination formulation of artemisinin of which there is only one: Artemether-Lumefantine (Coartem®). Although this option is expensive the Task Force has suggested that more cost-effective options could be explored when they become available. Currently Tanzania has funds from Round 4 of the GFATM for procurement of Coartem. The funds available from Round 4 of the GFATM is USD $54,201,787, 85 percent of which will be used for procuring ACT (Coartem). The end date for this grant is May 31, 2007, after which other sources for procuring ACTs will need to be identified.

The NMCP used SP estimates at sentinel sites to give information on the number of malaria cases every month. These estimates were used to calculate the quantities of ACTs needed in Tanzania. They have ordered 8.7 million courses of treatment of Coartem from Novartis through WHO (MMSS) for the first 6 months of implementation. These will be delivered in two shipments in January and March 2006 respectively. A second order will be placed of the same quantity for the following six months. The NMCP plans to begin ACT implementation in April 2006 after receiving the first two shipments of Coartem. The country hopes to use the experience from the SP change to implement a country wide implementation using staggered deliveries of the treatments to the health facilities.

Communication and mass campaigns for the change to ACTs at national and community levels will be done by PSI and Tanaam, however detailed plans have not been done.

The first draft of the new treatment guidelines which include ACTs has been completed and it is currently being circulated for comments both inside and outside the country. The draft will be used as an orientation guide during the first training of trainers in mid-August 2005 (beginning in Iringa) after which they will be finalized. Resources for printing of the new guidelines are available as part of the GFATM grant.

A revision of the new Tanzania National Formulary[4] is currently at the printing level. Therefore, an addendum incorporating the new recommendations will be made. The National Essential Drugs List of Tanzania (NEDLT) is also currently being revised and will need to incorporate the new treatment however these processes will only begin when an official announcement of the new policy is made.

The change to ACT will require the re-training of approximately 9,200 health workers by the NMCP and IMCI. NMCP will use a cascade training scheme beginning with national trainers in August 2005 through to the peripheral levels. It is expected that this will be complete in November 2005. Upon finalization of the new guidelines the IMCI training manuals, charts and algorithms, the reproductive health guidelines and any other guidelines with a malaria component will then be revised to include the new ACT as well as issues of laboratory diagnosis.

The NMCP course is a three-day course focusing on the new ACT treatment, intermittent preventive treatment (IPT) in pregnancy and drug management (which includes a component of inventory management). Costs for training all health workers in the country in the NMCP course have been estimated at around USD $1.2 million (training in IPT is being done through the Tanzania Voucher Scheme by World Vision and CARE).

There is little provision in the entire scheme for follow up and supervision after initial training has been done. While an extension of the World Vision/Care contract will enable them to do this for ITNs and IPT for one year, there are no provisions for case management follow up.

According to the MoH the agreement with GFATM, Coartem® will be purchased through WHO. However, WHO charges a 3 percent overhead cost. The NMCP believes that purchasing directly from Novartis will produce savings. It is unclear whether Novartis would be willing to sell directly to national programs at the WHO rate outside the WHO mechanism.

NMCP partners for ACT policy implementation include:

- IHDRC (Pharmacovigilance and to measure the effect of policy implementation)
- NIMR
- TFDA (regulatory, QC, Pharmacovigilance)
- PSI (Mass media)
- TaNaam (Communication in communities)
- CHMT (Implementation)
- Communities (Implementation)

Other challenges identified by the NMCP that are still under discussion are compliance and ensuring rational drug use, the treatment of choice in pregnant women and children < 5kg. Drug

[4] Last revised in 1998

management is also a challenge as currently two systems of distribution are operating in the country; the push and pull system. Discussions are underway with MSD to determine incorporating ACTs within existing distribution systems. The NMCP recognizes a need to strengthen inventory management and drug management at the district pharmacy and health facility levels.

While Coartem and other artemisinins are currently available in the private sector at very high prices, the NMCP recognizes that given that a large proportion of the population accesses treatment for malaria in the private sector, there will be a need to develop a strategy for distributing and subsidizing ACTs in this sector. A recent observation in the CDC IMPACT trial found that the availability of ACTs in Rufiji district increased public sector utilization by 20%. However, the long-term impact of this is unclear.

The NMCP was under the impression that the 6-dose packaging of Coartem needed a separate registration with the TFDA, however, discussions with TFDA determined that this was not necessary (see under TFDA below).

MSD

Mr. Missanga Muja (Procurement Manager and Acting Procurement Director)
Mr. Dickson Mwamwembe (Director of Logistics)

The Medical Stores Department (MSD) is responsible for procurement, storage and distribution of medicines to all public sector facilities. Some Mission facilities also get their medicinal supplies from MSD. For this service, MSD charges the MoH 15% of the shipment costs. Only drugs that are under the National Essential Drugs List of Tanzania (NEDLT) are supplied.

The procurement of Coartem as described above will be done under WHO-agreed procurement mechanisms with Novartis. Unless the government is able to negotiate direct procurement from Novartis, the Medical Stores Department's (MSD) responsibility will begin when the product lands in Tanzania. MSD will be responsible for clearance, storage and distribution (and re-packaging, if needed) of all health products for the MoH. Usually it takes 14-21 days for goods from arrival at the port to storage at MSD.

While MSD has a system of open competitive tendering for all government procurements, the government policy allows for single or limited source products (as in the case of ACTs) to be procured without open tenders.

The MSD has national and zonal warehouses and while currently, there is little storage capacity to accommodate large numbers of stocks, they have recently acquired an additional warehouse that will be used for malaria and other selected drug products.

Two systems of distribution exist currently in Tanzania; the "push" system which uses Essential Drug kits and the "pull" or indent system. In the former, each level of health facility receives a pre-determined quantity of kits of standard content while in the latter facilities decide on the quantity of products that are required and order these from MSD accordingly. Tanzania is in the process of converting the entire country to a pull system. So far, 47 districts out of a total of 120

are implementing a pull system while the rest still receive kits. It is expected that all the districts will convert to the indent system by 2007.

MSD distributes health commodities to all the MSD zonal stores which supply the districts. The responsibility of MSD ends at district level. The District Medical Officer's (DMO) office supplies health facilities within the district.

Although orders are placed by MSD annually (following the annual tender), kits are delivered every two months. In addition, MSD keeps 2 months of buffer stock. Under the indent system, deliveries are done every 3 months and three months of buffer stock is kept at MSD. Anything with an expiry date of less than 3 months is not issued.

Health facilities send orders directly to MSD, but the DMO distributes them from the district level downwards. The health facilities are theoretically supposed to send copies of the orders to the DMO, but in practice they do not. The district has its own funds for purchase of the drugs. However, the bottom line is fixed according to the kit budget.

The contents of the kits are determined by the Drugs and Therapeutics committee. Under the push system, the NMCP instructs the MSD what quantities of antimalarials to include in the kits. Currently, the kits contain SP, amodiquine and quinine. The SP for malaria treatment will be replaced with Coartem. However, consumption data for SP for IPT only is not available and the quantity of SP to replace has not been determined yet. Kit items have not been revised yet. SP quantities have already been reduced partly because excess quantities had previously been supplied due to errors in calculating need[5]. Amodiaquine has not started to be phased out yet but it is expected that quantities will start to be reduced.

A new tender for kits is being prepared for October 2005. It is expected that these new kits will contain the revised list of antimalarials. Expected delivery is April/May 2006 (6 months after tender). This coincides with the expected date of implementation of the new ACTs. It will be crucial for MSD and the NMCP to liaise and plan closely so that the facilities have the new first line drug at the same time as the IEC messages are transmitted.

Meetings between the MSD and the NMCP were conducted two weeks before this rapid assessment to discuss the logistics of supplying the new ACTs. As Coartem procurement is carried out under a different system from the other drugs in the kits and the kits already arrive packed at MSD, there are two options; the kits will either have to be repacked by MSD so that the Coartem can be placed in the kits or, there will need to be an additional kit for the Coartem. There have been discussions that suggest that the latter option may be more feasible due to the bulky nature of the prepackaged Coartem.

There is a repackaging facility at MSD. The cost for re-packaging (for items under the indent system) is Tsh 20,000 (approx. USD 20) per facility. It has not been determined what the charge

[5] When Tanzania changed from chloroquine to SP, the quantity of SP to be ordered was substituted tablet for tablet for SP resulting in excess SP stock (chloroquine tablets are taken every 6 hours over the course of four days while SP tablets are taken as a single dose).

would be if the new kits will have to be re-packaged. MSD has requested NMCP to provide a sample in order to determine costs.

There are no plans for additional security for ACTs. ARVs and narcotics are kept in locked cages within the warehouses and trucks are always locked during the dispatch process.

Currently, when MSD receives products the batch numbers and expiry dates are recorded and there is a system for issuing products that have shorter expiry dates first. There are no systems for product exchange among the districts. However, near-expiry products in a facility may be given to another facility within the same district that is likely to consume it before it expires. However, this will depend on the initiative of the district pharmacist and there are no set procedures to ensure that this occurs. There are no systems to return near expired products to the MSD. Expired products are destroyed at the district level.

MSD also does random sampling and takes the samples to the Tanzania Food and Drugs Authority (TFDA) or the government laboratory for testing. In addition some samples are taken at random and subjected to testing using a minilab at MSD itself. TFDA also randomly collects samples from MSD for testing (particularly antimalarials, TB medicines, antiretrovirals and some antibiotics).

There is a gap in information exchange from the MSD level to the peripheral levels mainly due to the decentralized system. Currently with the indent system, there are delays with facilities bringing orders due to a lack of experience with forecasting needs. Furthermore, Drug Management Information Systems (DMIS) are poor and there is a lack of consolidated data at the various levels on utilization or consumption.

TFDA

Mr. R.L. Mhangwa; Director of Product Registration
Mr. Henry Irunde; Pharmacovigilance
Mr. Chukilizo; Head of Drug Registration

TFDA authorizes import of all products which are also inspected for quality at the entry point. The registration procedure also requires product quality testing and GMP inspection. However, in the case of Coartem which has been prequalified by WHO, the TFDA has an exemption mechanism for inspection requirements.

There is a three-tier quality assurance mechanism for drugs in Tanzania. In addition to samples being subjected to drug quality testing during product registration, they are also subjected to quality testing at ports of entry. In addition, the TFDA carries out random post-marketing surveillance to test for product quality at MSD and in the private sector.

Currently all medicinal products for consumption in Tanzania must be registered by the TFDA. Products are registered for five years after which the registration must be renewed. The process of renewal is simple and requires the manufacturer to fill a series of forms. New data are usually not required. Rapid Diagnostic Tests are governed by the laboratory services department of the MoH and do not require registration by TFDA. Coartem (artemether/lumefantrine, 20/120) was registered by TFDA in June 2000. The product registration was due for renewal in June 2005. At

the time of conducting the interview with the head of registration at TFDA, no renewal for Coartem had been received. Although the registration for Coartem has expired, the TFDA will honor their registration provided the manufacturer submits the renewal soon.

WHO now recommends that Coartem be used for three days (6-doses) in high transmission areas such as Tanzania instead of the original recommended duration of two days (4 doses). For the purposes of registration, the increased duration of treatment requires a notification by the manufacturer to TFDA by way of a letter. No new registration for the change in duration of treatment is requires and no new dossiers need to be submitted.

Currently, 14 artesunate products are registered as the TFDA, 13 as monotherapies and 1 as a combination with mefloquine (manufactured by Mepha), 12 artemether products (including Coartem) and 4 dihydroartemisinin products.

In Tanzania the doctor: population ratio is 1: 25,000. Therefore, in order to ensure access the first line antimalarial must be available at the lowest levels of care the population seeks treatment. At the dispensary level where there is no doctor, any medicine with a prescription only legal status may not be supplied to this level. It will thus be necessary to deregulate the Coartem from a prescription only medicine to a over the counter medicine (or on the General Sales List)[6]. This is done by the National Therapeutics Committee. There are currently discussions being carried out at the MoH on this process. In order for this process to occur, the NMCP must make this recommendation to the Chief Pharmacist who in turn will present this to the National Therapeutic Committee (NTC). On agreement, they will signal the TFDA for adjustment of the National Formulary and the Essential Drugs Lists for the various levels of public facility. At the TFDA this must go through the legal committee. This process can take a few months as the NTC does not meet often.

In addition to its functions as a regulatory body and product quality assurance, the TFDA also is responsible for monitoring of adverse drug reactions (ADRs). The pharmacovigilance system in Tanzania is based on a system of passive reporting. All facilities and manufacturers are provided with stamp prepaid forms to return to zonal centers in referral hospitals for reporting any ADRs to drugs. There are plans to work with Ifakara to develop a combined system of active and passive systems. Under this system, regional hospitals will collect this information and send it to the central level. There are plans for conducting a training of health workers in ADR monitoring as well as equipping centers with computers connected to the central level to enable easy information flow. Funds for this were requested as part of the round 4 proposal to the GFATM.

Management Sciences for Health (MSH)

Dr. Romauld Mbwasi

Discussions were held with Dr. Mbwasi of MSH who is implementing the MSH/MoH Accredited Drug Dispensing Outlet (ADDO) pilot strategy. The ADDOs are privately operated outlets

[6] There are four categories of drugs in Tanzania; Narcotics, Prescription Only Medicines, Pharmacy Only Medicines and Over the Counter Medicines/General Sales List

authorized to sell a range of essential drugs classified as prescription-only with training and supervision from national and local drugs regulatory authorities. ADDOs will eventually replace Part II drug stores. Currently only about 100 ADDOs exist in the Ruvuma Region where the concept was pilot-tested by TFDA and MSH's Strategies to Enhance Access to Medicines project (SEAM).

The main suppliers to the private sector are Salama pharmaceuticals, JD pharmacy and Nkurumah pharmacy which supply mostly generics. 42% of children < 5 years obtain treatment from shops even though mothers know that treatment will be free in the public sector. 16% of the population lives > 10km from a health facility. There is a limited distribution system at the levels where the poorest of the population live. Therefore, while the availability of a more effective drug in the public health facilities may increase their utilization, there will be a significant proportion of the population that will still seek treatment for malaria in the private sector. To ensure equitable access to these populations at risk of malaria, it will be essential to find innovative ways to deliver antimalarials though the private sector at an affordable price.